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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,514	02/19/2002	Ludwig Volkel	52203	3431
26474	7590	05/15/2006	EXAMINER	
NOVAK DRUCE DELUCA & QUIGG, LLP 1300 EYE STREET NW SUITE 400 EAST TOWER WASHINGTON, DC 20005			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,514	VOLKEL ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 February 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4,6,7,10-16,18,19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,6,7,10-16,18,19 and 21-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/06 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1,4,6,7,10-13,15,16,18,19,23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The claims state that the diffraction lines are at d=3.80 Angstroms and 4.55 Angstroms, however, the most intense lines are presumably at 3.40 and 4.70 Angstroms, far outside of the diffraction lines. The Examiner is confused as to how the most intense diffractions lines can occur outside of the diffraction lines. Clarification is required.
4. Regarding claim 10, it is unclear if the choline ascorbate is being claimed, as the drug or the claims comprises further components. Clarification of this claim is required.

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5. Claim 23 appears to be missing essential steps. Choline ascorbate is made from the process, yet choline is never added to the mixture of ascorbic acids, solvents and water. The only mention of the compound is in step c), where the choline ascorbate is crystallized. However, it is unclear where the choline ascorbate comes from. The previous steps do not create it since they are only mixing ascorbic acid, trimethylamine, water and ethylene oxide. The Examiner is uncertain where and how the choline ascorbate is formed. If the process forms the choline ascorbate then why is choline not present in the process? Clarification of this is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1,2,4,6,7,10-16,18,19 and 21-26 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Klein et al (USPN 2,870,198 hereafter '198) and Spires et al (USPN 4,394,377 hereafter '377). The claims are drawn to a choline ascorbate formulation. The choline ascorbate is incorporated into a feed composition for ruminant animals. The claims also recite a method of preparing the choline salt comprising reacting an organic acid with solvents.

2. The '198 patent teaches the crystallization of choline salts (abstract). Isolation with ethylene oxide and trimethylamine, at low temperature (below 40⁰C) is well known in the art as seen in '198 (col. 2, lin. 18 – 59), preferably from 10-20⁰C (*Ibid.*). The crystals are anhydrous

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and are crystallized at the lowest temperatures of the operating process (example 1). Organic acids such as anhydrous citric acid, and tartaric acid are used in the reaction (examples). Choline is a well-known additive in feed compositions and pharmaceuticals (col. 1, lin. 15-35). It would have been within the level of skill in the art to substitute a specific organic acid into the process of the '198 patent in order to arrive at another choline salt. This can be seen in the '337 patent.

3. The '377 discloses a feed for ruminant animals 'comprising crystalline choline salts made with organic and inorganic acids (abstract). According to '377, the crystalline salts including choline ascorbate are available commercially (col. 3, lin. 62 – col. 4, lin. 7). The crystals can be incorporated into ruminant animal supplement (col. 4, lin. 28 – 35, col. 14, lin. 4-13). The '377 patent further discloses that organic solvents such as methanol and ethylene oxide are common within the production of choline ascorbate (col. 3, lin. 49-55). This process of crystallization is well known in the art and can be seen in '198.

4. With regard to the crystal characteristics and melting points recited by the claims, it remains the position of the Examiner that since the process for making the crystals is the same, the crystals would inherently have the same characteristics. The process calls for an organic acid, trimethylamine and ethylene oxide along with choline to be reacted at low temperatures. The '198 patent teaches this exact process. The only difference is the specific organic acid. The process of the '198 patent produces anhydrous crystals useful for pharmaceutical and animal feeds, identical to those crystals of the instant claims. Applicant is invited to show how the crystals created by the process of the '198 patent would be different than those of the instant claims. Until such evidence can be presented the claims will remain obviated by the art.

5. Also the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

6. With these things in mind one of ordinary skill in the art would have been motivated to process choline ascorbate as seen in '198 in order to produce stable crystals that are anhydrous and have high levels of purity. It would have been obvious to combine these crystals resulting from the '198 patent with the ruminant animal feed formulations of '377 in order to produce an improved feed formulation. It would have been obvious to combine the teachings of these references in order to provide a feed composition with improved stability and nutritional value.

Response to Arguments

7. Applicant's arguments filed 2/27/06 have been fully considered but they are not persuasive. Applicant argues that:
- a. The process of Klein is different and produces a different product.
8. Regarding this argument, it remains the position of the Examiner however that the procedures are substantially identical except for the use of different organic acids. Applicant points to the reflux temperature of the alcohol and acid mixture. Applicant argues that this

temperature is beyond the range of the claimed process and would produce a different crystal as shown in the Hoffman reference. However the Examiner directs Applicant to later in the same example where the mixture is cooled to 5⁰C where the crystallization takes place. Further the Klein crystals are anhydrous, as the crystals of the instant claims. The only difference between the crystals in the organic acid reacted in the process. However it remains the position of the Examiner that such a substitution of organic acids is well within the level of skill in the art. Applicant argues that it is unexpected to arrive at the crystals of the present invention. Yet the process of the '198 patent operates with the same solvents, and temperature ranges allowing for crystallization at the same stages. It remains the position of the Examiner that if the same components are processed in the same way. Then the products must have the same properties. The '198 patent provides the process and the '377 provides the established knowledge of combining ascorbic acid to make choline ascorbate. Until evidence of a patentable distinction can be provided, the claims will remain obviated.

Correspondence

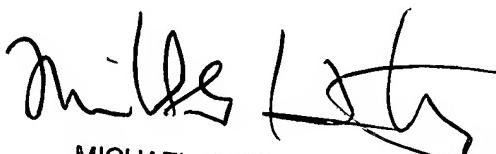
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER